

**SUMMARY ANALYSIS OF RESPONSES TO CONSULTATION ON AMENDMENTS TO
LICENCE CONDITIONS 17 & 36**

Table of Contents	Page
Introduction	3
Table 1 - General comments on proposals	4
Table 2 - Comments on changes to licence condition 17	5
Table 3 - Comments on changes to licence condition 36	8
Table 4 - Summary of wider comments on proposed changes	14

Introduction

On 12 May 2011 Dr Mike Weightman, HM Chief Inspector of Nuclear Installations, wrote to all nuclear site licence holders to consult them on amendments to the licence conditions attached to nuclear site licences that ONR were proposing to ensure that the Nuclear Safety Directive 2009/71/Euratom (NSD) was fully transposed in Great Britain. The letter, the attachments explaining the changes, and an impact assessment, were published on the ONR website inviting other interested parties to comment.

ONR received twenty responses to the consultation exercise which it considered ahead of finalising the proposed amendments to licence conditions 17 and 36, and the note explaining the changes. This document summarises the responses, the decisions, and actions taken by ONR in light of the consultation exercise.

The final revised licence conditions were forwarded to all licensees for attachment to their current nuclear site licences by the Directive's implementation deadline of 22 July 2011. In August 2011 a Project Assessment Report (PAR), which described the process of implementing the NSD in relation to Great Britain, was made available on the ONR website together with a final impact assessment (IA), amended licence conditions and note explaining the changes. The summary analysis document completes the set of ONR documents relating to the consultation exercise.

Further work is in hand to provide the opportunity for licensees to contribute to the development of guidance for the amended licence conditions 17 & 36. ONR would like however to take this opportunity to thank all respondents for their contribution to the consultation process.

Table 1 - General comments on proposals

Mike Weightman’s consultation letter set out the basis for the proposal to amend licence conditions. It explained that whilst, in Great Britain, most of the provisions of the Nuclear Safety Directive 2009/71/Euratom (NSD) are transposed by the current nuclear safety regime, in particular through the Nuclear Installations Act 1965 (NIA65) and the standard set of 36 licence conditions attached to nuclear site licences, ONR had identified some small changes that were needed to two of the standard licence conditions to ensure the NSD was fully implemented.

General comments from respondents are set out in table 1.

	Summary of comments	Respondents	ONR Response
i.	ONR’s search for a pragmatic and proportionate solution to UK compliance with the Directive was supported but requested an opportunity to be involved in influencing the ONR guidance/notes for inspectors.	12	ONR welcomes the acknowledgement of its efforts to implement the NSD in a proportionate way which seeks to minimise the potential burdens on the industry.
ii.	No need to make any changes to licence conditions and that the current nuclear licensing regime was fully compliant with the requirements of the Directive.	1	ONR’s detailed analysis in developing the proposals has ensured that the measures put forward are the minimum necessary to fully implement the NSD in Great Britain and avoid the risk of legal challenge by the European Commission (EC).

Table 2 - Changes to licence condition 17 proposed by the ONR consultation

Annex B of the consultation letter explained that Article 6(4) of the NSD required that licensees establish and implement management systems that give due priority to nuclear safety, and that the Regulator subject these to regular verification. The ONR proposal was to revise licence condition 17 so that licensees would be required expressly to “establish and implement management systems that give due priority to nuclear safety”. ONR also proposed the requirement that licensees make adequate “quality assurance” arrangements for all matters which may affect safety should be amended so that it refers to “quality management” arrangements.

A summary of responses to this ONR proposal are set out in table 2.

	Summary of comments	Respondents	ONR Response
i.	LC 17 changes could be adopted with minor process enhancements.	1	ONR welcomed the confirmation by some that the proposals reflected current practice.
ii	The changes reflect current practice and concurred with the ONR view that the change would have a nil cost impact.	2	
iii.	Making nuclear safety a priority in the management system was important. The respondents commitment to safety was reflected in their adoption of external certification to BS OHSAS 18001 ¹ and subscription to the principles of IAEA GS ² .	1	

¹ OHSAS 18001 is an Occupation Health and Safety Assessment Series for health and safety management systems intended to help an organizations to control occupational health and safety risks (<http://www.ohsas-18001-occupational-health-and-safety.com/what.htm>).

² The International Atomic Energy Agency (IAEA) is authorised to establish or adopt standards of safety for the protection of human health and the minimisation of danger to life and property, and to provide for these standards. The safety standards are encoded to their coverage and the acronym ‘GS’ relates to ‘General safety’ standards (http://www-pub.iaea.org/MTCD/publications/PDF/Pub1252_web.pdf).

iv.	Concern expressed that 'Management Systems' could be interpreted as more than one management system. The use of the singular (i.e. 'Management System') was proposed.	1	<p>ONR's view is that whilst we encourage licensees to have an integrated management system we do not require it. 'Management Systems' is therefore more appropriate as it covers circumstances where licensees may have more than one system.</p> <p>ONR has also amended 17(3) to include the text: "such part or parts of" in relation to quality management arrangements as well as management systems.</p>
v.	The introduction of 'nuclear safety' in LC 17(1) was questioned.	1	Licence condition 17(1) now refers to 'safety' rather than 'nuclear safety'. Use of the word 'safety' satisfies implementation requirements.
vi	The use of the term 'quality' was questioned as it did not, in the respondents view, add value. The respondent's organisation aimed to have an integrated management system which encompassed quality, safety, environment etc.	1	<p>ONR's consultation Annex B document (http://www.hse.gov.uk/nuclear/news/2011/attachments/annex-b.pdf) explained that, in ONR's view, the change from 'quality assurance' arrangements to 'quality management' brought the licence condition language more in line with modern standards (e.g. IAEA) and used by industry.</p>
vii	Unclear why the proposal referred to management systems and quality management arrangements.	1	
viii.	If the amended licence condition now extends to management systems and quality management arrangements (rather than simply to quality assurance arrangements) a degree of materiality should be introduced to LC 17(4). It was needed to prevent any change to the licensees safety-related management systems or processes or procedures...being construed as an infringement of the licence condition.	1	ONR was not persuaded by the suggestion. To add the word 'material' into LC 17(4), as proposed, would bring with it uncertainties about the legal definition of 'material' and was not consistent with the suite of LC's generally.

ix.	There was no demonstrable need to introduce a new requirement for a licensee to “establish and implement management systems which give due priority to nuclear safety” because such a requirement has existed for over 20 years via the standard set of licence conditions that are attached to all nuclear site licences in the UK.	1	ONR agree that in practice, its inspectors will, as they do now, continue to monitor the licensees’ safety management systems and the effectiveness of the quality assurance/management arrangements. The Directive required that the licensee establish and implement management systems that give due priority to nuclear safety, and that the Regulator subject these to regular verification. The revised version of licence condition 17 makes that requirement explicit. This was deemed necessary to avoid the risk of legal challenge by the EC.
x.	Welcome the opportunity to comment on the ONR’s interpretation of “due priority” either within a revised guidance to inspectors (T/INS/017) or elsewhere.	2	ONR has sent the revised guidance on licence condition 17 (T/INS/017) to those who expressed an interest in commenting on it.
xi.	Concern was expressed about the potential interpretation of management system. If applied to all licensee’s activities (commercial, HR, financial etc), the regulator, (in theory) could call in any part of the management system and approve (or freeze). This appears to give a very broad power which is not required to satisfy the conditions of the directive.	1	ONR would not approve a suite of management arrangements. Approval would be used selectively, if at all and, if used, it would be applied in such a way that only arrangements at a particular level would be frozen. This recognises that licensees’ management arrangements change regularly. We would not wish to use the power of 'approval' to constrain these changes. We do not therefore anticipate material change or impact on the licensee's business.

Table 3 - Changes to licence condition 36 proposed by the ONR consultation

Annex B to the consultation letter explained Article 6(5) of the NSD required a licensee to provide and maintain adequate financial and human resources to ensure it can fulfil its obligations in respect of nuclear safety. The purpose of the existing licence condition 36 had been to ensure that the licensee has adequate arrangements in place to control any change to its organisational structure or resources which could affect safety. The ONR proposal was to amend licence condition 36 to encompass the licensee’s responsibility to have and maintain adequate financial and human resources.

A summary of responses to this ONR proposal are set out in table 3.

	Summary of comments	Respondents	ONR Response
i.	LC 36 human resources amendments could be adopted with minor process enhancements. Requested that ONR make inspection procedures and guidance available that is consistent with the consultation letter and its attachments; and that the impact assessment be updated to reflect any further cost information.	2	ONR welcome the acknowledgement of its efforts to implement the NSD in a proportionate way. An updated IA is available at http://www.hse.gov.uk/nuclear/news/2011/may-consultation.htm
ii.	Confirmed that the financial resource documents referenced in the explanatory note were typical of documents produced by a commercial organisation and would be readily available. They do not therefore expect to undertake any additional work to produce extra supporting documents.	1	
iii.	Content with proposed changes to LC 36 and did not see any significant problems with its introduction.	1	
iv.	The proposed amendment to LC 36 “appears to state what is already accepted wisdom”.	1	

vi.	Did not anticipate the changes leading to significant change in regulatory behaviour and noted that they do not expect to be routinely asked for financial information.	2	
vii.	Was not convinced of the need to amend the licence conditions if it resulted in no difference in practice. Respondents opinion was that existing guidance material provided “a comprehensive platform for regulatory assessment on the subject of adequate human resources” and so no additional guidance was needed.	1	The NSD requires that the licensee demonstrates an ongoing capability to provide and maintain adequate financial and human resources to ensure nuclear safety throughout the lifetime of the site and not just at the point of gaining a licence. The regulator must be in position to ensure this is so beyond the granting of the licence.
viii.	<p>Strongly opposed the changes for the following reasons:</p> <ul style="list-style-type: none"> • any requirement placed upon the licensee to demonstrate the ability to provide and maintain adequate financial resources, should be a requirement for granting a nuclear site licence and not a requirement placed on the licensee via licence conditions; • the current nuclear licensing arrangements already covered the human resources requirement and so there was no need for a change; and • there was no need to change LC 36 or its title to have a specific licence condition for “organisational capability”. Historically this requirement has been adequately covered by the licensing process and the requirements of the existing conditions attached in the “standard licence”, and this remains the case. 	1	<p>The ONR view is that the process of granting a licence is not sufficient to address the requirement to maintain financial resources throughout the lifetime of the site but that using licence conditions to give effect to this requirement is sufficient to implement the directive.</p> <p>The amendment to the licence condition makes the NSD’s requirement to maintain human resources explicit within the regulatory framework. The explicit expression of this requirement within the UK regulatory framework allows ONR to demonstrate that the requirement is fully implemented in Great Britain.</p> <p>The title organisational capability reflects the Directive’s requirements for the licensees to provide and maintain financial and human resources have been put together with the existing requirement in LC 36 to require the licensee to implement adequate arrangements to control any change to its organisational structure or resources which may affect safety.</p>

ix.	The regulatory approach needs to recognise that in some cases the company which holds the site licence may differ from that which controls the management and financial framework under which the relevant duties are discharged.	1	ONR's view, as stated in Annex B of the consultation guidance document, is that where the licensee's budget is controlled by another body, financial, and other resourcing arrangements, are likely to be set out in the management contracts between the licensee and the controlling body (e.g. the lifetime plan (LTP)). ONR anticipates that the controlling body will co-operate with the licensee in ensuring the adequacy of the resources needed for safety. The licensee however remains responsible for nuclear safety under the terms of its nuclear site licence and the conditions attached to it. ONR will consider this issue again in the development of its guidance material.
x.	Need to avoid overlap in regulatory requirements and avoid unintended scope creep.	4	ONR will address this point in the development of its guidance material.
xi.	Questioned how the proposed changes to the Energy Act 2008 might impact on the role of the ONR under the proposed licence conditions.	1	ONR's view is that the proposed changes to the Energy Act 2008 do not have any effect on ONR's statutory role with regard to the application of the licence conditions.
x.	Queried the links between the Secretary of State's (SoS) powers to propose or agree a modification to Funded Decommissioning Programmes (FDP) and those of the regulators (as per the licence conditions changes) in terms of financial arrangements by operators to cover all requirements under an FDP and a licence.	1	The legislation in the Energy Act 2008 requires an operator to set out in a Funded Decommissioning Programme the operator's plans for decommissioning, waste management and waste disposal and the estimates of the costs of these activities.
xi.	Wanted an explanation of the different roles/powers of the SoS and the ONR in ensuring funding is available in the proposed FDP and the relevant licence conditions; and the role of the ONR in the FDP process.	1	Funding requirements covered by the Directive and the licence condition relate directly to a licensee's ability to provide and maintain an adequate degree of nuclear safety on each licensed site - throughout the site's lifetime.

			ONR acknowledge that there will be some commonality of regulatory interests with regard to the sufficiency of funding for decommissioning activities and as a result ONR is a statutory consultee to the Secretary of State in relation to an operator's Funded Decommissioning Programme.
xii.	As part of its commitment to openness and transparency the ONR should provide examples of areas where there may be commonality of interests between the regulators/SoS and operator finances.	1	ONR and DECC officials are in regular contact to ensure any proposals on interfacing on FDP issues are aligned; the details of which will be worked out in further discussions. However, ONR cannot predict the extent to which an operator's demonstration of licence condition compliance will reference a Decommissioning and Waste Management Plan (DWMP) developed for FDP in advance of a site-specific FDP being submitted. This will be a matter for ONR to discuss with each licence applicant. If common documentation can meet some requirements of both the DECC and ONR regulatory regimes, then this will minimise the regulatory burden on an operator and reflects good regulatory practice.
xiii.	As new build licensees will also be subject to additional funding obligations such as FDP, ONR should develop guidance for inspectors which recognises the different funding structures and additional funding obligations of new build licensees.	1	ONR will consider this in the development of its guidance material.
xiv.	ONR should provide greater clarity to licensees on when it may draw on financial expertise, including on the frequency and likely cost.	1	ONR has said in all consultation material that our intention is that such instances will be rare, and that any ONR guidance will reflect that intention.
xv.	The RIA had not comprehended the full impact of the financial resource change to LC36.	1	Given ONR's assurances that its call on financial expertise would be rare, it is difficult to provide more information on frequency and costs in the final IA.

xvi.	The expert advice on financial resources should not be cost recoverable.	1	If it is necessary for ONR to seek expert financial advice on financial resources it is no different from seeking other expert advice and so it would recover its costs from licensees.
xvii.	<p>Several concerns/questions were raised about financial resources:</p> <ul style="list-style-type: none"> • what measures are taken in the event of a sudden decrease in funding or insolvency? • compliance with legal duties to maintain an appropriate level of nuclear safety is not likely to be sufficient evidence of compliance with the licence condition regarding the licensee's existing financial resources; or that a company always having the necessary finance could be taken as a 'given': • the changes to LC36 do not make explicit the need to demonstrate the ability to maintain 'adequate' financial and human resources - by the company and associated companies; and 	1	<p>The responsibility for nuclear safety lies solely with the nuclear site licence holder. ONR is responsible for all nuclear sector regulation across the UK. The issue of company solvency does not fall to ONR.</p> <p>It is the responsibility of the licence holder to advise the Regulator of changes to its own arrangements that may affect safety, and seek the appropriate permissions to do so. This responsibility may not be delegated to any other party. ONR expects this to be demonstrated through establishing, implementing management system(s). In its draft guidance on inspection of arrangements on licence condition 17 (para 5.2 T/INS/017) it states that:</p> <p style="padding-left: 40px;">“LC 17 (1) requires licensees to establish and implement management systems which give due priority to nuclear safety. The licensee must therefore ensure that any of its management system(s) processes (e.g. financial, commercial, project, safety or environmental) give due priority to nuclear safety. Inspectors may continually inspect this part of the licence condition during their routine activities by monitoring the outputs from the various management system processes and identifying any actions or decisions which did not give due priority to, or adversely affected, nuclear safety...”</p> <p>ONR acknowledge that many licensees have funding</p>

			<p>arrangements with other corporate bodies or bodies. However, it remains the responsibility of the licensee to ensure its compliance with all licence conditions. ONR is encouraged that the majority of respondents to consultation (including licensees and corporate/controlling bodies) expressed a strong desire to work with ONR on guidance on the requirement to provide and maintain financial resources.</p>
--	--	--	--

Table 4 - Summary of wider comments on proposed changes

A number of broader queries/observations were raised and are set out in table 4.

	Summary of comments	Respondents	ONR Response
i.	Is there any relationship between the proposed regulatory changes to licence conditions 17 and 36 and the proposals to implement changes to the Paris and Brussels conventions on nuclear third party liability?	1	No.
ii.	There is no explanation on how the public or Parliament gets access to information which provides assurances that the relevant financial provisions are in place or can be fully met.	1	<p>ONR's role is the regulation of nuclear licensed sites. In this role ONR, as an agency of the Health and Safety Executive, is accountable to the Secretary of State for Energy and Climate Change, who is in turn, accountable to Parliament.</p> <p>Licensees are responsible for demonstrating nuclear safety on a licensed site. This now includes an explicit requirement to demonstrate that it has the human and financial resources necessary to ensure nuclear safety. The explanatory note issued as part of the consultation package set out the nature of the information that licensee's might use to do this. (http://www.hse.gov.uk/nuclear/news/2011/attachments/annex-b.pdf)</p> <p>Further guidance is being developed and industry will have an opportunity to influence that process. ONR guidance on the licence conditions is already publicly available on the ONR webpages:</p>

			<p>1. Compliance inspection - Technical inspection guides http://www.hse.gov.uk/foi/internalops/nsd/tech_insp_guides/</p> <p>2. Permissioning inspection - Technical assessment guides http://www.hse.gov.uk/foi/internalops/nsd/tech_asst_guides/</p> <p>3. Technical assessment guides http://www.hse.gov.uk/nuclear/tagsrevision.htm</p>
iii.	In future ONR should explain the basis of its consultations.	1	<p>The Governments' consultation code acknowledges that where an exercise is very narrow, and the level of interest highly specialised, there are other means by which input can be sought from interested parties, and that such engagement work is not the subject of the consultation code.</p> <p>The consultation exercise on amendments to licence condition 17 and 36 was undertaken to meet HSE's obligations under Section 4(4) of the Nuclear Installations Act 1965 (NIA65); to "consider any representations by an organisation representing persons having duties upon the site."</p> <p>However, as the driver for these amendments was the implementation of the Nuclear Safety Directive, it was appropriate to provide the opportunity for wider comment on the proposals. Future ONR exercises of this type will make this point clear in the consultation documentation.</p>

